

What is claimed is:

1. A disposable device for axenically culturing and harvesting cells and/or tissue in at least one cycle, said device comprising a sterilisable disposable container having a top end and a bottom end, which container may be at least partially filled with a suitable sterile biological cell and/or tissue culture medium and/or axenic inoculant and/or sterile air and/or required other sterile additives, said container comprising: (i) a gas outlet for removing excess air and/or waste gases from said container; (ii) an additive inlet for introducing said inoculant and/or said culture medium and/or said additives into said container; and characterized in further comprising (iii) a reusable harvester comprising a flow controller for enabling harvesting of at least a desired portion of said medium containing cells and/or tissues when desired, thereby enabling said device to be used continuously for at least one further consecutive culturing/harvesting cycle, wherein a remainder of said medium containing cells and/or tissue, remaining from a previous harvested cycle, may serve as inoculant for a next culture and harvest cycle, wherein said culture medium and/or said required additives are provided.

2. The device of claim 1, wherein said disposable container is transparent and/or translucent.

3. The device of claim 1, further comprising an air inlet for introducing sterile gas in the form of bubbles into said culture medium through a first inlet opening, wherein said air inlet is connectable to a suitable gas supply.

4. The device of claim 3, wherein said air inlet is for introducing sterile gas more than once during culturing.

5. The device of claim 4, wherein said air inlet is for continuously introducing sterile gas.

6. The device of claim 4, wherein a plurality of different gases are introduced at different times and/or concentrations through said air inlet.

7. The device of claim 1, said harvester comprising a contamination preventer for substantially preventing introduction of contaminants into said container via said harvester.

8. The device of claim 1, wherein said container is non-rigid.

9. The device of claim 8, wherein said container is made from a non-rigid plastic material.

10. The device of claim 9, wherein said material is selected from the group comprising polyethylene, polycarbonate, a copolymer of polyethylene and nylon, PVC and EVA.

11. The device of claim 9, wherein said container is made from a laminate of more than one layer of said materials.

12. The device of claim 9, wherein said container is formed by fusion bonding two suitable sheets of said material along predetermined seams.

13. The device of claim 3, wherein said air inlet comprises an air inlet pipe extending from said inlet opening to a location inside said container at or near said bottom end thereof.

14. The device of claim 3, wherein said at least one air inlet comprises a least one air inlet pipe connectable to a suitable air supply and in communication with a plurality of secondary inlet pipes, each said secondary inlet pipe extending to a location inside said container, via a suitable inlet opening therein, for introducing sterile air in the form of bubbles into said culture medium.

15. The device of claim 14, wherein said device comprises a substantially box-like geometrical configuration, having an overall length, height and width.

16. The device of claim 15, wherein the height-to-length ratio is between about 1 and about 3, and preferably about 1.85.

17. The device of claim 15, wherein the height to width ratio is between about 5 and about 30, and preferably about 13.

18. The device of claim 16, wherein said device comprises a support aperture substantially spanning the depth of said device, said aperture adapted to enable said device to be supported on a suitable pole support.

19. The device of claim 14, further comprising a support structure for supporting said device.

20. The device of claim 19, wherein said support structure comprises a pair of opposed frames, each said frame comprising upper and lower support members spaced by a plurality of substantially parallel vertical support members suitably joined to said upper and lower support members.

21. The device of claim 20, wherein said plurality of vertical support members consists of at least one said vertical support member at each longitudinal extremity of said upper and lower support members.

22. The device of claim 20, wherein said frames are spaced from each other by a plurality of spacing bars releasably or integrally joined to said frames.

23. The device of claim 21, wherein said spacing bars are strategically located such that said device may be inserted and removed relatively easily from said support structure.

24. The device of claim 20, wherein said lower support member of each said frame comprises at least one lower support adapted for receiving and supporting a corresponding portion of said bottom end of said device.

25. The device of claim 24, wherein each said lower support is in the form of suitably shaped tab projecting from each of the lower support members in the direction of the opposed frame.

26. The device of claim 20, wherein said frames each comprise at least one interpartitioner projecting from each frame in the direction of the opposed frame, for to pushing against the sidewall of said device at a predetermined

position, such that opposed pairs of said interpartitioner effectively reduce the width of said device at said predetermined position.

27. The device of claim 26, wherein said interpartitioner comprise suitable substantially vertical members spaced from said upper and lower support members in a direction towards the opposed frame with suitable upper and lower struts.

28. The device of claim 19, wherein, said support structure comprises a plurality of castors for transporting said devices.

29. The device of claim 3, wherein at least some of said air bubbles comprise a mean diameter of between about 1 mm and about 10 mm.

30. The device of claim 3, wherein at least some of said air bubbles comprise a mean diameter of about 4 mm.

31. The device of claim 1, wherein said container comprises a suitable filter mounted on said gas outlet for substantially preventing introduction of contaminants into said container via said gas outlet.

32. The device of claim 1, wherein said container further comprises a suitable filter mounted on said additive inlet for substantially preventing introduction of contaminants into said container via said additive inlet.

33. The device of claim 1, further comprising a contamination preventer comprising a U-shaped fluid trap, wherein one arm thereof is aseptically mounted to an external outlet of said harvester by suitable aseptic connector.

34. The device of claim 1, wherein said harvester is located at the bottom of said bottom end of said container.

35. The device of claim 1, wherein said harvester is located near the bottom of said bottom end of said container, such that at the end of each harvesting cycle said remainder of said medium containing cells and/or tissue automatically remains at said bottom end of said container up to a level below the level of said harvester.

36. The device of claim 1, wherein said remainder of said medium containing cells and/or tissue is determined at least partially according to a distance  $d_2$  from the bottom of said container to said harvester.

37. The device of claim 1, wherein said remainder of said medium containing cells and/or tissue comprises from about 2.5% to about 45% of the original volume of said culture medium and said inoculant.

38. The device of claim 37, wherein said remainder of said medium containing cells and/or tissue comprises from about 10% to about 20% of the original volume of said culture medium and said inoculant.

39. The device of claim 1, wherein said bottom end is substantially convex.

40. The device of claim 1, wherein said bottom end is substantially frusta-conical.

41. The device of claim 1, wherein said container comprises an internal fillable volume of between about 5 liters and about 200 liters, preferably between about 50 liters and 150 liters, and preferably about 100 liters.

42. The device of claim 1, wherein said device further comprises suitable attacher for attaching said device to a suitable support structure.

43. The device of claim 42, wherein said attacher comprises a loop of suitable material preferably integrally attached to said top end of said container.



44. The device of claim 1, adapted to plant cell culture.

45. The device of claim 44, wherein said plant cell culture comprises plant cells obtained from a plant root.

46. The device of claim 45, wherein said plant root is selected from the group consisting of *Agrobacterium rhizogenes* transformed root cell, celery cell, ginger cell, horseradish cell and carrot cell.

47. A battery of said devices, comprising at least two said disposable devices of claim 3.

48. The battery of claim 47, wherein said devices are supported by a suitable support structure via an attacher of each said device.

49. The battery of claim 47, wherein said gas outlet of each said device is suitably connected to a common gas outlet piping which optionally comprises a blocker for preventing contaminants from flowing into said devices.

50. The battery of claim 49, wherein said blocker comprises a suitable filter.

51. The battery of claim 47, wherein said additive inlet of each said device is suitably connected to a common additive inlet piping having a free end optionally comprising suitable aseptic connector thereat.

52. The battery of claim 51, wherein said free end is connectable to a suitable supply of medium and/or additives.

53. The battery of claim 47, wherein said harvester of each said device is suitably connected to a common harvesting piping having a free end optionally comprising suitable aseptic connector thereat.

54. The battery of claim 53, further comprising contamination preventer for substantially preventing introduction of contaminants into said container via said common harvesting piping.

55. The battery of claim 54, wherein said contamination preventer comprises a U-shaped fluid trap, wherein one arm thereof is free having an opening and wherein the other end thereof is aseptically mountable to said free end of said common harvesting piping via suitable aseptic connector.

56. The battery of claim 55, wherein said free end of said U-tube is connectable to a suitable receiving tank.

57. The battery of claim 47, wherein said air inlet of each said device is suitably connected to a common air inlet piping having a free end optionally comprising suitable aseptic connector thereat.

58. The battery of claim 57, wherein said free end is connectable to a suitable air supply.

59. A method for axenically culturing and harvesting cells and/or tissue in a disposable device comprising :

providing said device which comprises a sterilisable transparent and/or translucent disposable container having a top end and a bottom end, which container may be at least partially filled with a suitable sterile biological cell and/or tissue culture medium and/or axenic inoculant and/or sterile air and/or other sterile required additives, said container comprising:

(i) gas outlet for removing excess air and/or waste gases from said container;

(ii) additive inlet for introducing said inoculant and/or said culture medium and/or said additives into said container;

(iii) reusable harvester comprising suitable flow controller for enabling harvesting of at least a portion of said medium containing cells and/or tissue

when desired, thereby enabling said device to be used continuously for at least one further consecutive cycle, wherein a remainder of said medium containing cells and/or tissue, remaining from a previously harvested cycle may serve as inoculant for a next culture and harvest cycle, wherein said culture medium and/or said required additives are provided;

providing axenic inoculant via said harvester;

providing sterile said culture medium and/or, sterile said additives via said additive inlet;

optionally illuminating said container with external light; and

allowing said cells and/or tissue to grow in said medium to a desired yield.

60. The method of claim 59, further comprising:

allowing excess air and/or waste gases to leave said container continuously via said gas outlet.

61. The method of claim 60, further comprising:

checking for contaminants and/or the quality of the cells/tissues which are produced in said container: if contaminants are found or the cells/tissues which are produced are of poor quality, the device and its contents are disposed of;

if contaminants are not found, harvesting said desired portion of said medium containing cells and/or tissue.

62. The method of claim 61, wherein while harvesting said desired portion, leaving a remainder of medium containing cells and/or tissue in said container, wherein said remainder of medium serves as inoculant for a next culture/harvest cycle.

63. The method of claim 62, further comprising:  
providing sterile said culture medium and/or sterile said additives for the next culture/harvest cycle via said additive inlet; and  
repeating the growth cycle until said contaminants are found or the cells/tissues which are produced are of poor quality, whereupon the device and its contents are disposed of.

64. The method of claim 59, wherein said device further comprises an air inlet for introducing sterile air in the form of bubbles into said culture medium through a first inlet opening connectable to a suitable sterile air supply, said method further comprising the step of providing sterile air to said air inlet during the first and each subsequent cycle.

65. The method of claim 64, wherein said sterile air is supplied continuously throughout at least one culturing cycle.

66. The method of claim 64, wherein said sterile air is supplied in pulses during at least one culturing cycle.

67. A method for axenically culturing and harvesting cells and/or tissue in a battery of disposable devices comprising:

providing a battery of devices of claim 55, and for at least one said device thereof:

providing axenic inoculant to said device via a common harvesting piping;

providing sterile said culture medium and/or sterile additives to said device via common additive inlet piping;

optionally illuminating said device with external light; and

allowing said cells and/or tissue in said device to grow in said medium to a desired yield.

68. The method of claim 67, further comprising:

allowing excess air and/or waste gases to leave said device continuously via common gas outlet piping;

checking for contaminants and/or the quality of the cells/tissues which are produced in said device: if in said device contaminants are found or the cells/tissues which are produced are of poor quality, said harvester of said device is closed off preventing contamination of other said devices of said battery;

if in all of said devices of said battery contaminants are found or the cells/tissues which are produced therein are of poor quality, all the devices and their contents are disposed of;

if contaminants are not found and the quality of the produced cells/tissues is acceptable, for each harvestable device, harvesting a desired portion of said medium containing cells and/or tissue via common harvesting piping and said contamination preventer to a suitable receiving tank.

69. The method of claim 68, wherein a remainder of medium containing cells and/or tissue remains in said container, wherein said remainder serves as inoculant for a next culture/harvest cycle; and the method further comprises:

providing sterile said culture medium and/or sterile said additives for the next culture/harvest cycle via said additive inlet to form a growth cycle.

70. The method of claim 69, wherein said growth cycle is repeated until said contaminants are found or the cells/tissues which are produced are of poor quality for all of said devices of said battery, whereupon said contamination preventer is disconnected from a common harvester and said devices and their contents are disposed of.

71. A method for axenically culturing and harvesting cells and/or tissue in a battery of disposable devices comprising:

providing a battery of devices of claim 58, and for at least one said device thereof:

providing axenic inoculant to said device via common harvesting piping;  
providing sterile said culture medium and/or sterile additives to said device via common additive inlet piping;  
providing sterile air to said device via common air inlet piping;  
optionally illuminating said device with external light; and  
allowing said cells and/or tissue in said device to grow in said medium to a desired yield.

72. The method of claim 71, further comprising:

allowing excess air and/or waste gases to leave said device continuously via common gas outlet piping; and

checking for contaminants and/or the quality of the cells/tissues which are produced in said device: if in said device contaminants are found or the cells/tissues which are produced are of poor quality, said harvester of said device is closed off preventing contamination of other said devices of said battery; if in all of said devices of said battery contaminants are found or the cells/tissues which are produced therein are of poor quality, all the devices and their contents are disposed of; if contaminants are not found and the quality of the produced cells/tissues is acceptable, the device is considered harvestable.

73. The method of claim 72, further comprising:



harvesting at least a desired portion of said medium containing cells and/or tissue for each harvestable device via common harvesting piping and said contamination preventer to a suitable receiving tank.

74. The method of claim 73, wherein a remainder of medium containing cells and/or tissue remains in said container, wherein said remainder serves as inoculant for a next culture/harvest cycle; and the method further comprises:

providing sterile said culture medium and/or sterile said additives for the next culture/harvest cycle via said additive inlet to form a growth cycle.

75. The method of claim 74, wherein said growth cycle is repeated until said contaminants are found or the cells/tissues which are produced are of poor quality for all of said devices of said battery, whereupon said contamination preventer is disconnected from a common harvester and said devices and their contents are disposed of.

76. A device for plant cell culture, comprising a disposable container for culturing plant cells.

77. The device of claim 76, wherein said disposable container is capable of being used continuously for at least one further consecutive culturing/harvesting cycle.

78. The device of claim 77, further comprising:  
a reusable harvester comprising a flow controller for enabling harvesting of at least a desired portion of medium containing cells and/or tissues when desired, thereby enabling said device to be used continuously for at least one further consecutive culturing/harvesting cycle.

79. The device of claim 78, wherein said flow controller maintains sterility of a remainder of said medium containing cells and/or tissue, such that said remainder of said medium remaining from a previous harvested cycle, serves as inoculant for a next culture and harvest cycle.

80. A method for culturing plant cells, comprising:  
culturing plant cells in a disposable container.

81. The method of claim 80, wherein said disposable container comprises an air inlet for introducing sterile gas or a combination of gases.

82. The method of claim 81, wherein said sterile gas comprises air.

83. The method of claim 82, wherein said sterile gas combination comprises a combination of air and additional oxygen.

84. The method of claim 83, wherein said additional oxygen is added separately from said air.

85. The method of claim 84, wherein said additional oxygen is added a plurality of days after initiating cell culture.

86. The method of claim 81, wherein said sterile gas or combination of gases is added more than once during culturing.

87. The method of claim 81, wherein said air inlet is for continuously introducing sterile gas.

88. The method of claim 81, wherein a plurality of different gases is introduced at different times and/or concentrations through said air inlet.

89. The method of claim 81, further comprising:  
aerating said cells through said inlet.

90. The method of claim 89, wherein said aerating comprises administering at least 1.5 L gas per minute.

91. The method of claim 80, further comprising:

providing sufficient medium for growing said cells.

92. The method of claim 91, wherein sufficient medium is at a concentration of at least about 125% of a normal concentration of medium.

93. The method of claim 91, further comprising:

adding media during growth of the cells but before harvesting.

94. The method of claim 93, further comprising:

adding additional media at least about 3 days after starting culturing said cells.

95. The method of claim 93, further comprising:

replacing media completely at least about 3 days after starting culturing said cells.

96. The method of claim 91, wherein said medium comprises a mixture of sugars.

97. The method of claim 91, wherein said medium comprises a larger amount of sucrose than normal for cell culture.

98. The method of claim 80, wherein said plant cells produce a recombinant protein.